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| 10/606,299      | 06/24/2003  | Xiaoyi Min           | A03P1046US01        | 2874             |

36802 7590 05/10/2006

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| EXAMINER |
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KAHELIN, MICHAEL WILLIAM

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3762

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/606,299

Applicant(s)

MIN ET AL.

Examiner

Michael Kahelin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☒ Claim(s) 1-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10032005; 06242003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether Applicant is claiming an implantable medical device, method, or system. Furthermore, claims 1-19 mix two different statutory classes. It is suggested to use "[i]n an implantable medical device".
3. In regards to claim 7, "detecting cardiac ischemia" is lacking antecedent basis. Examiner has interpreted the claim to depend on claim 6.
4. In regards to claim 15, "the onset of ischemia" is lacking antecedent basis.
5. In regards to claims 20 and 22, the "bipolar lead" and "lead" are inferentially included, rendering it unclear whether these elements are actually part of the claimed invention.
6. In regards to claim 22, the claim is incomplete because no element is set forth to calculate total energy values.

### ***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite a lead "mounted within the atria", amounting to an inferential inclusion of the atria as part of the claimed invention. As part of the human body, the atria are nonstatutory subject matter. It is suggested to claim leads "adapted to be" mounted within the atria.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 6, 18 and 20 are rejected under 35 U.S.C. 102(b) as anticipated by Alferness (US 5,531,768, hereinafter "Alferness") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Alferness in view of DuFault (US 4,799,486, hereinafter "DuFault"). Alferness discloses the essential features of the claimed invention including the following:

12. In regards to claims 1 and 20, Alferness discloses sensing signals using a lead mounted within the atria (44 to 46), sensing (38 to 44) signals having potentially both atrial and ventricular events, eliminating the first signal from the second (col. 4, line 21), and examining the remaining events to identify repolarization events (col. 5, line 19). Alferness further discloses that the first electrode configuration spans the atria and the second configuration spans an atrium and a ventricle (Fig. 1), and one signal is subtracted from the other signal (col. 4, lines 1-29), which would inherently leave substantially only ventricular events. Alternatively, DuFault teaches of acquiring a local bipolar signal, acquiring a far-field unipolar signal, and subtracting the two to acquire a signal that contains EGM data from only the chamber of interest. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Alferness' invention with a means to eliminate far-field atrial signals to

acquire a desired ventricular signal that contains less noise, and is representative of only the chamber of interest.

13. In regards to claim 6, Alferness (or Alferness in view of DuFault) determines energy values (potential energy) to detect cardiac ischemia (col. 5, line 21).

14. In regards to claim 18, Alferness' (or Alferness in view of DuFault's) ventricular lead is a bipolar lead operating in a unipolar mode (Fig. 1).

15. Claims 8, 15-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness (or Alferness in view of DuFault).

16. In regards to claim 8, Alferness (or Alferness in view of DuFault) discloses the essential features of the claimed invention except for detecting cardiac ischemia to predict AMI. It is well known in the art to detect cardiac ischemia to predict AMI to avoid the serious risks associated with AMI. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Alferness' (or Alferness in view of DuFault's) invention by detecting ischemia to predict AMI to avoid the serious risks associated with AMI.

17. In regards to claims 15 and 16, Alferness (or Alferness in view of DuFault) discloses the essential features of the claimed invention except for generating an internal warning signal to patient tissue to indicate ischemia. It is well known in the art to provide tactile warnings with implanted devices for various indications to allow the patient to seek medical care. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Alferness' (or

Alferness in view of DuFault's) invention with a means to generate an internal warning signal to patient tissue to indicate ischemia.

18. In regards to claims 17 and 19, Alferness (or Alferness in view of DuFault) discloses the essential features of the claimed invention except for sensing unipolar signals using a unipolar lead in a ventricle or an atrium. It is well known in the art to utilize various combinations of unipolar and bipolar leads in the atria and ventricles to provide systems that can sense and provide therapy in a very flexible manner.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize various combinations of unipolar and bipolar leads in the atria and ventricles to provide systems that can sense and provide therapy in a very flexible manner.

19. Claims 2-5 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness (or Alferness in view of DuFault) in view of Stadler et al. (US 6,381,493, hereinafter "Stadler"). Alferness (or Alferness in view of DuFault) discloses the essential features of the claimed invention except for identifying repolarization peaks and specifying windows based on the peaks; detecting depolarization peaks and specifying repolarization windows based on the event peaks; detecting ischemia based on whether repolarization is caused by a paced or intrinsic beat; comparing a current normalized energy value of the repolarization to depolarization/evoked response to a running average and determining whether the difference exceeds a sinus beat threshold; or ignoring repolarization events associated with ectopic beats and fused beats. Stadler teaches of identifying repolarization peaks and specifying windows

based on the peaks (col. 32, line 58) to accurately detect the t-wave irrespective of the heart rate; detecting depolarization peaks and specifying repolarization windows based in the event peaks (col. 19, line 65) to detect the t-wave based on the easily recognizable r-wave; detecting ischemia based on whether repolarization is caused by a paced or intrinsic beat (col. 29, line 21) to provide accurate diagnosis based on the differing repolarization characteristics of paced and intrinsic beats; comparing a current normalized energy value of the repolarization to depolarization/evoked response to a running average and determining whether the difference exceeds a sinus beat threshold (col. 6, line 45; col. 23, line 10; and col. 29, line 21) to avoid the need to calibrate the device for each individual patient; and ignoring repolarization events associated with noise and arrhythmia (it is well known in the art that ectopic beats and fused beats are examples of noise and arrhythmia) (col. 23, line 53). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Alferness' (or Alferness in view of DuFault's) invention by identifying repolarization peaks and specifying windows based on the peaks to accurately detect the t-wave irrespective of the heart rate; detecting depolarization peaks and specifying repolarization windows based in the event peaks to detect the t-wave based on the easily recognizable r-wave; detecting ischemia based on whether repolarization is caused by a paced or intrinsic beat to provide accurate diagnosis based on the differing repolarization characteristics of paced and intrinsic beats; comparing a current normalized energy value of the repolarization to depolarization/evoked response to a running average and determining whether the difference exceeds a sinus beat threshold



to avoid the need to calibrate the device for each individual patient; and ignoring repolarization events associated with ectopic and fused beats.

20. In regards to claims 3 and 5, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the window end points as taught by Stadler with the claimed end points because applicant has not disclosed that the claimed end points provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the end points as taught by Stadler because both end points facilitate the acquisition of the t-wave. Therefore, it would have been an obvious matter of design choice to modify the end points to obtain the invention as specified in the claims.

21. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness (or Alferness in view of DuFault) in view of Zanetti et al. (US 5,159,932, hereinafter "Zanetti"). Alferness (or Alferness in view of DuFault) discloses the essential features of the claimed invention except for detecting ischemia based on detecting the maximum slopes of repolarization events. Zanetti discloses determining the maximum slope of a t-wave (col. 9, line 65) to effectively differentiate t-waves for the purpose of ischemia detection. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Alferness' (or Alferness in view of DuFault's) invention by determining the maximum slope of a t-wave to effectively differentiate t-waves for the purpose of ischemia detection.

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22. Claims 9, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alferness (or Alferness in view of DuFault) in view of Lerner (US 5,213,106, hereinafter "Lerner"). Alferness (or Alferness in view of DuFault) discloses the essential features of the claimed invention except for determining the total energy of a t-wave by summing the points of the cardiac signal to detect ischemia. Lerner teaches of deriving the integral of a t-wave (col. 5, line 43) to find the total energy as an indicator of fatigue or ischemia (col. 3, line 48). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Alferness' (or Alferness in view of DuFault's) invention by deriving the integral of a t-wave to find the total energy as an indicator of ischemia.

### ***Double Patenting***

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 1, 6, 7, 8, and 15-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 10/603,398, hereinafter "'398". Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application's claims are more narrow and meet the limitations of the broader claims of this application.

25. In regards to claim 8, '398 discloses the essential features of the claimed invention except for detecting cardiac ischemia to predict AMI. It is well known in the art to detect cardiac ischemia to predict AMI to avoid the serious risks associated with AMI. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify '398 by detecting ischemia to predict AMI to avoid the serious risks associated with AMI.

26. In regards to claims 15 and 16, '398 discloses the essential features of the claimed invention except for generating an internal warning signal to patient tissue to indicate ischemia. It is well known in the art to provide tactile warnings with implanted devices for various indications to allow the patient to seek medical care. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide '398 with a means to generate an internal warning signal to patient tissue to indicate ischemia.

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27. In regards to claims 17, 18 and 19, '398 discloses the essential features of the claimed invention except for sensing unipolar signals using a unipolar lead in a ventricle or an atrium. It is well known in the art to utilize various combinations of unipolar and bipolar leads in the atria and ventricles to provide systems that can sense and provide therapy in a very flexible manner. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide '398 with various combinations of unipolar and bipolar leads in the atria and ventricles to provide systems that can sense and provide therapy in a very flexible manner.

28. Claims 2-5 and 10-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 10/603,398 in view of Stadler et al. (US 6,381,493, hereinafter "Stadler"). '398 discloses the essential features of the claimed invention except for identifying repolarization peaks and specifying windows based on the peaks; detecting depolarization peaks and specifying repolarization windows based on the event peaks; detecting ischemia based on whether repolarization is caused by a paced or intrinsic beat; comparing a current normalized energy value of the repolarization to depolarization/evoked response to a running average and determining whether the difference exceeds a sinus beat threshold; or ignoring repolarization events associated with ectopic beats and fused beats. Stadler teaches of identifying repolarization peaks and specifying windows based on the peaks (col. 32, line 58) to accurately detect the t-wave irrespective of the heart rate; detecting depolarization peaks and specifying repolarization windows based in the event peaks (col. 19, line 65) to detect the t-wave based on the easily

recognizable r-wave; detecting ischemia based on whether repolarization is caused by a paced or intrinsic beat (col. 29, line 21) to provide accurate diagnosis based on the differing repolarization characteristics of paced and intrinsic beats; comparing a current normalized energy value of the repolarization to depolarization/evoked response to a running average and determining whether the difference exceeds a sinus beat threshold (col. 6, line 45; col. 23, line 10; and col. 29, line 21) to avoid the need to calibrate the device for each individual patient; and ignoring repolarization events associated with noise and arrhythmia (it is well known in the art that ectopic beats and fused beats are examples of noise and arrhythmia) (col. 23, line 53). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify '398 by identifying repolarization peaks and specifying windows based on the peaks to accurately detect the t-wave irrespective of the heart rate; detecting depolarization peaks and specifying repolarization windows based in the event peaks to detect the t-wave based on the easily recognizable r-wave; detecting ischemia based on whether repolarization is caused by a paced or intrinsic beat to provide accurate diagnosis based on the differing repolarization characteristics of paced and intrinsic beats; comparing a current normalized energy value of the repolarization to depolarization/evoked response to a running average and determining whether the difference exceeds a sinus beat threshold to avoid the need to calibrate the device for each individual patient; and ignoring repolarization events associated with ectopic and fused beats.

29. Claims 9, 21, and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 10/603,398 in view of Lerner (US 5,213,106, hereinafter "Lerner"). '398 discloses the essential features of the claimed invention except for determining the total energy of a t-wave by summing the points of the cardiac signal to detect ischemia. Lerner teaches of deriving the integral of a t-wave (col. 5, line 43) to find the total energy as an indicator of fatigue or ischemia (col. 3, line 48). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify '398 by deriving the integral of a t-wave to find the total energy as an indicator of ischemia.

This is a provisional obviousness-type double patenting rejection.


### ***Conclusion***

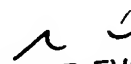
30. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Weinberg et al. (US 6,539,259) is one of many teachings of eliminating undesired events, Cox et al. (US 4,679,144) is one of many teachings that ischemia is a predecessor of AMI, Nelson (US 6,155,267) is one of many teachings of a tactile warning signal, DeCote, Jr. (US 4,674,509) is one of many teachings of utilizing unipolar and bipolar electrodes in a variety of configurations, and Douglas (US 3,828,768) is one of many teachings of classifying ectopic and fused beats as arrhythmia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK  
  
5/5/06

  
GEORGE R. EVANISKO  
PRIMARY EXAMINER  
5/5/06